



Update on HRSA/OPTN Activities in Pancreas and Islet Transplantation

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Transplant Programs

- 246 kidney
- 123 liver
- 138 pancreas
- 45 pancreas islet cell
- 46 intestine
- 134 heart
- 60 heart/lung
- 68 lung



Islet Program Membership

- Earlier this year, Board approved criteria developed by the OPTN Kidney-Pancreas Transplantation Committee for islet program membership, and for transplant physician and surgeon experience and training



Islet Program Membership Criteria

- Must be located at a center approved to perform whole pancreas transplants
- Must submit data on patients transplanted
- Must report the disposition of the islets (transplanted, discarded, other use)
- Must have adequate clinical and laboratory facilities as defined by FDA, and document required IND application is in effect



Islet Program Membership Criteria (cont.)

- Must have a collaborative relationship with physician qualified to cannulate the portal system
- Islets must be isolated in a facility with an FDA IND application in effect\
- Additional criteria for programs in centers without a whole pancreas transplant program



OPTN Policy 3.2 Waiting List

- All patients who are potential recipients of deceased organ transplants must be listed on the computer Waiting List
- OPTN Members shall not provide organs to non-member transplant centers



Waiting List and Transplants

Candidates waiting as of November 5, 2004:

- 1648 pancreas
- 2451 kidney/pancreas
- 324 islet

Transplants performed in 2003:

- 502 pancreas
- 870 kidney-pancreas



Allocation of Pancreata for Islet Transplantation

- Current OPTN allocation algorithm for pancreata gives local priority for whole organ transplantation
- OPTN has approved requests for variances giving higher priority for local allocation of pancreata for use in islet transplantation
- Approved variances generally limit the number of pancreata diverted for use in islet transplantation



Variances Under Final Rule

- Experimental policies that test methods of improving allocation
- Accompanied by a research design
- Include plans for data collection and analysis
- Time limited
- Subject to same approval process as standard policies



New Pancreas Allocation Algorithm

- Candidates ranked by length of time on the waiting list
- Highest priority to 0-mismatch and highly sensitized candidates
- If no 0-mismatch candidates, then
- Local isolated pancreas, or combined kidney-pancreas, or combined solid organ-islet
- If a pancreas still is not accepted, then allocate based on donor age and BMI as follows:



New Pancreas Allocation Algorithm (cont.)

Donor age ≤ 50 years AND BMI ≤ 30 kg/m²

- Regional isolated or combined K-P; then
- National isolated or combined K-P; then
- Facilitated isolated or combined K-P; then
- Local, then regional, then national islet; then
- Research



New Pancreas Allocation Algorithm (cont.)

Donor age > 50 years OR BMI > 30 kg/m²

- Local, then regional, then national islet; then
- Regional then national for whole pancreas transplantation; then
- Research



Ongoing Issues/Concerns

- Allocation priority for whole organ transplants may mean less than ideal pancreata available for islet transplants
- Islet transplantation may require more than one donor to treat a patient
- Apparent mismatch between local availability of potential pancreas donors and local need



Ongoing Issues/Concerns *(cont.)*

- Cost/reimbursement issues—inadequate yield; difficult to place
- Whole pancreas transplantation is an accepted therapy—how does islet transplantation compare
- Patients adequately informed about both options (whole pancreas vs. islet transplant)



OPTN/UNOS Pancreas Consensus Conference

- OPTN/UNOS Consensus Conference on Pancreas Allocation for Whole Organ and Islet Transplantation
- January 23-24, Miami Florida
- Goal: to discuss and develop OPTN/UNOS policy regarding pancreas and islet transplantation
- Invitees: leaders in the areas of organ allocation, whole organ pancreas transplantation and islet transplantation to discuss issues regarding the allocation, placement and reporting of both whole organ pancreas and islet transplants.



OPTN/UNOS Pancreas Consensus Conference (cont.)

4 Working Groups

1. Allocation Issues
2. Procurement Issues
3. Data Reporting/Regulatory Issues
4. Reimbursement Issues



OPTN/UNOS Pancreas Consensus Conference (cont.)

Proposed Process

- WGs will do some work in advance of meeting
- Overview presented to full group
- WG breakout sessions
- Full group reconvenes